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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,074	03/19/2001	Henry A. Lester	A-59891-2/RFT/JJD	8989

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FLEHR HOHBACH TEST ALBRITTON & HERBERT LLP  
Four Embarcadero Center - Suite 3400  
San Francisco, CA 94111-4187

EXAMINER
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PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/812,074	LESTER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Pak	1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13, 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

***Response to Amendment***

1. Amendment filed November 8, 2004 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed November 8, 2004, have been fully considered but they are not found persuasive.

***Claim Rejections - 35 USC § 112***

4. Claims 13 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recite "capable of specifically hybridizing" which is ambiguous because the hybridization conditions are relative term and the metes and bounds of conditions are not clear.

5. Claims 13 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass a method of using a genus of nucleic acid probes which will hybridize with a large genus of nucleic acid which encodes variant inward rectifier potassium channel proteins which is not disclosed in the specification nor to one of skilled in the art. The probes are not defined by any critical or definitive structural limitations. Claims encompass DNAs which hybridize to the aforementioned genus of DNAs and encode proteins defined by function alone without any critical or definitive structural limitations because of no structural limitation and the recitation of "hybridization" language. The specification only discloses a single species disclosed in SEQ ID NO:1. The specification does not disclose what structural features, other than the full length sequence of the single species of SEQ ID NO:1, must be retained in order to render a protein as an inward rectifier potassium channel. The specification fail to disclose what specific functions are considered to be definitive of retinoic acid receptor and what specific structures are critical to their retention. The claims are drawn to a genus that need only be related or retain a function that is "characteristic" of a potassium channel without a definition of what functions are characteristic and what structures other than the full length sequence of SEQ ID NO:1 are required for said functions. Without said information, the single species cannot be representative of such a broad genus. Claimed method uses nucleic acid probes which encompass a large genus of probes from other potassium channel alleles or variants whose function has yet to be identified including from different species of animal because the structure of

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the newly identified naturally occurring channel is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. The essential feature of the invention is the single species of DNA encoding SEQ DI NO:2. The specification with a single species does not provide support for the claimed genus because *Eli Lilly* held that one skilled in the art could not envision the structure of the genus of proteins in other species such as human or the genus of mammalian or vertebrate proteins. In the same manner, one skilled in the art cannot envision the genus of potassium channel structure and thus the specification does not provide adequate disclosure for the claimed genus.

Applicants argue that the specification provides description for one of skilled in the art to perform the method of hybridization. However, the specification does not provide details of the hybridization and one skilled in the art cannot envision all the possible nucleic acid with the functional limitation of the potassium channel.

### ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 13 and 39 of this application for the reasons provided above under the 35 USC 112 , first paragraph, above. See MPEP 706.02.

### ***Claim Rejections - 35 USC § 102***

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6. Claims 13 and 39 are rejected under 35 U.S.C. 102(a), 102(b) , and 102(e) as being anticipated by Jan et al. (US 5,670,335).

Jan et al. disclose a method of isolating a sample using nucleic acid probes to hybridize with a sample (columns 6, 9, and 13-14). Jan et al. disclose SEQ ID NO :4 which is identical to applicant's SEQ DI NO:2.

7. Claims 13 and 39 are rejected under 35 U.S.C. 102(a) and 102(b) as being anticipated by Kubo et al. (Nature, 1993).

Kubo et al. disclose a method of isolating a sample using nucleic acid probes to hybridize with a sample (figures 1 and 4; page 85). Kubo et al. disclose SEQ ID NO :4 which is identical to applicant's SEQ ID NO:2.

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

  
Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
18 March 2005